K032513
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OCT 3 0 2003

# 510(k) Summary of Safety and Effectiveness

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|---|---|
| Date: | August 12, 2003 |
| Submitter: | GE Medical Systems *Information Technologies*<br>8200 West Tower Avenue<br>Milwaukee, WI 53223 USA |
| Contact Person: | David Wahlig<br>Sr. Regulatory Affairs Specialist<br>GE Medical Systems *Information Technologies*<br>Phone: (262) 293-1705<br>Fax: (414) 918-8112 |
| Device: Trade Name: | T-Wave Alternans (TWA) Algorithm Option |
| Common/Usual Name: | ECG Analysis Algorithm |
| Classification Names: | Classification Name: 21 CFR 870.1425 Programmable diagnostic computer<br>Classification Number: 74 DQK |
| Predicate Devices: | K02338 T-Wave Alternans (TWA) Algorithm Option |
| Device Description: | T-Wave Alternans (TWA) Algorithm Option is a software algorithm that runs on GE Medical Systems *Information Technologies*' electrocardiographic equipment. |
| Intended Use: | The T-Wave Alternans (TWA) Algorithm Option is intended for use in a hospital, doctor's office or clinic environment by competent healthcare professionals for recording ST-T wave morphology fluctuations for patients who are undergoing cardiovascular disease testing.<br><br>T-Wave Alternans (TWA) describes an electrocardiographic (ECG) pattern that exhibits different ST/T-wave morphologies on alternating beats. The algorithm performs the measurement of this variation at an accuracy and resolution of 1-microvolt. The TWA Algorithm Option permits visual confirmation of TWA by displaying the original ECG along with representative complexes made from a moving average of every other beat.<br><br>The TWA Algorithm measurements have been found to be predictive of arrhythmic death and can be used for the purposes of risk stratification. The TWA Algorithm Option allows the user to specify the maximal heart rate for valid TWA measurements and the specific heart rate to be attained before TWA is measured.<br><br>The TWA Algorithm Option is intended to provide only the measurements of the fluctuations of the ST-T-waves. TWA measurements are intended for qualified personnel in evaluating the patient in conjunction with the patient's clinical history, symptoms, other diagnostic tests, as well as the professional's clinical judgment. No interpretation is generated. |
| Technology: | The T-Wave Alternans (TWA) Algorithm Option employs identical technology as the predicate device. |

Test Summary:

Tests results are identical. It is the same software as predicate device. Additional test results are provided via an independent, published study.

The T-Wave Alternans (TWA) Algorithm Option and its host electrocardiographic equipment comply with the voluntary standards as detailed in Section 9 of this submission.

The following quality assurance measures were applied to the development of T-Wave Alternans (TWA) Algorithm Option:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Code inspections
- Verification and Validation

Conclusion:

The results of these measures demonstrate that the T-Wave Alternans (TWA) Algorithm Option is as safe, as effective, and performs as well as the predicate software option. Results form an independent, published study provides additional support for this conclusion.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2003

GE Medical Systems Information Technologies
c/o Mr. David Wahlig
Sr. Regulatory Affairs Specialist
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K032513
Trade Name: T-Wave Alternans (TWA) Algorithm Option
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: August 12, 2003
Received: August 14, 2003

Dear Mr. Wahlig:

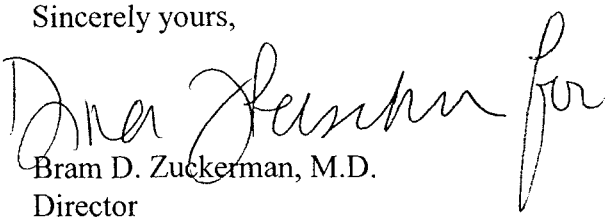
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K032513

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510(k) Number (if known): 510(k) filed on August 12, 2003

Device Name: T-Wave Alternans (TWA) Algorithm Option

Indications For Use:

The T-Wave Alternans (TWA) Algorithm Option is intended for use in a hospital, doctor's office or clinic environment by competent healthcare professionals for recording ST-T wave morphology fluctuations for patients who are undergoing cardiovascular disease testing.

T-Wave Alternans (TWA) describes an electrocardiographic (ECG) pattern that exhibits different ST/T-wave morphologies on alternating beats. The algorithm performs the measurement of this variation at an accuracy and resolution of 1-microvolt. The TWA Algorithm Option permits visual confirmation of TWA by displaying the original ECG along with representative complexes made from a moving average of every other beat.

The TWA Algorithm measurements have been found to be predictive of arrhythmic death and can be used for the purposes of risk stratification. The TWA Algorithm Option allows the user to specify the maximal heart rate for valid TWA measurements and the specific heart rate to be attained before TWA is measured.

The TWA Algorithm Option is intended to provide only the measurements of the fluctuations of the ST-T-waves. TWA measurements are intended for qualified personnel in evaluating the patient in conjunction with the patient's clinical history, symptoms, other diagnostic tests, as well as the professional's clinical judgment. No interpretation is generated.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K032513

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)